December 24, 2003

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Division of Documents Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket Nos. 02N-0276/02N-0278: Registration of Food Facilities and Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Sir/Madam:

The undersigned are a coalition of trade associations representing all tiers of the beverage alcohol industry. Members of our associations are involved in the production, importation, distribution/wholesaling, and retailing of beverage alcohol products that are sold throughout the United States.

On behalf of our beverage alcohol coalition, we appreciate the opportunity to submit our comments concerning the Food and Drug Administration's (FDA) interim final rules implementing the registration and prior notice requirements of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). At the outset, we want to commend the FDA for its outreach efforts and guidance documents to educate all affected parties about the requirements of FDA's rules.

In addition, we also want to commend FDA for its receptiveness to the comments and concerns of the food community, which was reflected in FDA's modifications to its initial proposals to implement the registration and prior notice provisions of the Bioterrorism Act. We also very much appreciate FDA's initiative to reopen its final rules in March 2004 to solicit once again comments from the food community in terms of how best to achieve the objectives of the Bioterrorism Act from the perspective of the Government and the regulated community.

As you know, the beverage alcohol industry is extensively regulated and, consequently, the industry has been very aggressive in terms of ensuring that all of its trading partners are fully acquainted with the provisions of the Bioterrorism Act and its requirements. FDA officials, particularly Mr. Louis J. Carson, Deputy Director of the Food Safety and Security Staff, FDA Center for Food Safety and Applied Nutrition, have been of extraordinary assistance in that regard. Our coalition that includes all segments and all tiers of our industry both here in the United States and around the world are indebted to the time and guidance imparted to us by Mr. Carson.

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Our specific comments regarding the interim rules are set forth below. One overarching comment pertains to the interim enforcement policy of FDA and the Customs & Border Protection (CBP). In that regard, it appears that various ports of arrival are taking different approaches to enforcement. Some ports are rejecting "prior notices" (PN) for technical information errors and some ports also are holding goods for such errors. In other ports, such as Baltimore and Norfolk, officials are more in an educational mode consistent with the enforcement guidance policy issued by FDA and CBP. We urge that FDA undertake the necessary action to ensure that all ports and all officials act in a similar fashion consistent with the enforcement guidance policy issued by the Government.

Obviously, it is our objective to ensure that all "t's" are crossed for each and every PN; however, with trading partners across the world that may not be the case in the early days since December 12, 2003, the effective date of the PN/registration interim final rules. Any and all action undertaken by FDA to achieve a consistent posture regarding enforcement greatly would be appreciated.

Finally, we urge that FDA and CBP conduct "cross-training" of their respective officials manning FDA or CBP help desks. This type of "cross-training" better will achieve the objectives of the Act by providing consistent advice and ensuring that FDA and CBP officials have integrated their approach toward implementing the interim final rules.

A. Registration Interim Final Rule

1. 24/7 emergency contact:

The interim final rule requires a facility to list an emergency contact phone number in the registration. In discussing this regulatory provision in the Federal Register notice, FDA states that an individual's name is not required, but that the information provided must enable FDA to contact a live person representing the facility 24 hours a day/7 days a week. FDA appropriately states in the interim final rule that "emergency contact information should be specific to the facility's already established emergency procedures."

Many businesses have in place emergency contact procedures in which a live person - although not answering the emergency contact phone number on a 24/7 basis - can return a call shortly after the call is received. For example, a company may provide for a live person to answer the telephone during business hours and, after business hours, the calls are forwarded to a computer operator that has the capability to contact a live person shortly thereafter, if necessary.

Given FDA's interim final rule and subsequent guidance, it is our understanding that procedures such as those described above meet the provisions of FDA's emergency contact requirements. To respond to any queries that may be raised by affected parties, we urge FDA to set forth these matters in its compliance documents provided to industry.

2. Quality control and other samples:

Quality control and other samples frequently are provided to U.S. businesses for quality control, quality assurance and other related purposes. These samples are not intended for consumption in the U.S. A U.S. business may test the samples on company laboratory equipment, analyze the samples for marketing purposes, and/or for organoleptic purposes "swirl and spit," but not ingest the samples.

Since these samples are not intended for consumption, the facility from which the sample was sent should not be required to register. We urge FDA to make it clear that facilities providing quality control samples are not required to register.

Finally, we request that FDA select a designation that a PN submitter/transmitter should include in the entries for the registration number that will identify that a registration number is not required; i.e., non-applicable (N/A) in PNs covering quality control and other samples. This course of action will reduce the possibility that these PNs will not be accepted for failure to provide registration numbers.

3. Separate registrations for separate goods produced at one facility:

Given the objective of FDA to communicate with the responsible party and to trace goods as quickly as possible, there are circumstances where separate registrations for different goods that happen to be produced at the same facility are warranted. For example, two distinct types of food products are produced at the same facility; however, separate title is taken to each of these two products immediately after being bottled. A separate staff of full-time employees is employed at that facility for the management and oversight only of those goods for which they have title. In addition, these employees are charged with shipping those goods from the foreign location to the U.S.

The owner of these goods is in the best position to track and trace their product. Consequently, more than one registration should be allowed in these unique circumstances. This would better achieve the Act's objectives and we urge FDA to provide for separate registrations in these circumstances.

4. Transport vehicles:

The interim final rule states that a transport vehicle is not a facility if it holds food in the "usual course of its business as a carrier." The key term "usual course of business," however, is not defined in the rulemaking. There are a host of varying circumstances where registration would not be required because the vehicle is holding food in the "usual course of its business as a carrier." Set forth below are typical transportation scenarios that would appear not to require registration and it would be of assistance to the regulated community to provide additional illustrations regarding what FDA deems to be "usual course of business" for a carrier.

a. Highway

- A local driver picks up a trailer and brings it to his company's yard to sit overnight for pick up and delivery the next day.

- A truck driver arrives at his destination only to be told by the customer that he cannot accept the load until the next day. The carrier takes the load to a trailer yard for delivery the next day

- A driver picks up a load for delivery to the customer the next morning. He stops to spend the night at a truck stop. The next morning the load is delivered.

b. Intermodal

- A carrier picks up a load and delivers it to the rail yard where the trailer sits one to two days before being placed on the train.

- A train arrives at the destination yard where the trailer sits one to two days before being released to the drayage carrier.

- A drayage carrier cannot secure a delivery appointment and must return to his yard where the trailer sits one to two days before delivering to the customer.

c. Rail

- A loaded car is taken by the local railroad to a switch track where the car sits one to two days before the Class 1 railroad takes the car to its yard.

- A car sits in the Class 1 rail yard one to two days before being made into the destination train.

- A car arrives at the destination Class 1 railroad and sits one to two days before delivery to the customer.

d. LTL (Less Than Truckload)

- A carrier picks up the shipment and brings it to his terminal for cross docking the next day.

- A carrier picks up the shipment and brings it to his terminal for cross docking and delivery the same day.

e. Air

- A carrier picks up a shipment and brings it to his terminal for departure the next day.

- A shipment arrives at the destination terminal and must wait one to two days for delivery.

B. Prior Notice Interim Final Rule

1. Imports erroneously placed on hold:

As discussed above, we have been apprised that certain food shipments have been placed on hold at certain ports on the grounds that the PNs are inadequate, and in other instances, ports are rejecting PNs for technical information errors. Under FDA's "Regulatory Action Guidance" (which is set forth in "Compliance Policy Guide"), the actions which FDA and Customs staff typically should be considering for inadequate PN in these circumstances (i.e., Category 3 under FDA's "Regulatory Action Guidance") are education/ communication and analysis of data for compliance action, but not refusal of entry, or rejection of the PN.

Consistent with the "Regulatory Action Guidance," we urge FDA to remove any holds placed upon imports of food products and any rejections of PNs based upon alleged PN deficiencies (if these do not fall within Categories 1 or 2) and allow entry of such products. We also recommend that FDA take all necessary steps to ensure that FDA and Customs personnel responsible for reviewing PNs and deciding appropriate compliance action at each and every port are fully apprised of FDA's "Regulatory Action Guidance" and that they implement that enforcement policy correctly and uniformly.

2. Contact person where issues or problems arise:

The regulatory provisions in the PN interim final rule are silent regarding which person(s) will be contacted by FDA and/or Customs when an issue or problem arises regarding a PN. We urge FDA to clarify that in these circumstances the Agency will contact the person that filed the PN - i.e., the submitter or the transmitter. By reason of his or her knowledge and/or access to the necessary information, as well as authority and responsibility to properly file the prior notice, the submitter or transmitter typically will be in the best position to take corrective action as expeditiously as possible. This course of action better will meet the objectives of the Bioterrorism Act, as well as avoid unnecessary burdens and delays to commerce that could result if FDA were to contact other persons (such as the carrier) that may not have the same capability to ensure that prompt action is taken.

3. Providing the PN confirmation number no later than arrival:

There may be circumstances where the ABI/ACS system for whatever reason is not functioning and a PN is submitted through the use of the FDA web portal system. To anticipate such an event, various companies are organizing contingency plans whereby the PN confirmation number will be included in the delivery order, which then will be faxed to the office of the steamship line at the port of entry so that the requisite paperwork is in hand when the product is offloaded from the carrier.

This contingency plan takes into account the unique circumstances posed by transporting goods by steamship line insofar as the Customs broker or purchaser may not always be able to send the PN confirmation number to the carrier prior to the carrier's arrival. These default procedures also would be followed for other modes of transport, if necessary.

This contingency scenario hopefully will not arise; nevertheless, we submit that the above-described procedures satisfy FDA's requirements that the PN confirmation number accompany the food when it "arrives in the United States" and be provided to Customs or FDA "upon arrival," and urge FDA to include this course of action in its compliance guidance documents.

4. A single PN for different sizes of the same brand

The current rule requiring a separate PN for each size of the same brand produced by the same manufacturer imposes a substantial and unnecessary burden upon the resources of the Government, as well as of industry. FDA can reduce the paperwork burdens of the current scheme substantially for both Government and industry, without impacting adversely upon the ability of FDA to trace imports, by allowing a single PN for different sizes of a manufacturer's brand.

By streamlining the current scheme in this manner, FDA also would enhance its ability, as well as that of industry, to focus resources more effectively upon achieving the purposes of the Act and ensuring no unnecessary delays and burdens upon trade. This suggestion also will reduce the "overloading" that early experience shows is occurring in PN filings.

5. Develop and implement measures to reduce the "overload" to the FDA PN program

Industry is experiencing delays in the processing of its PNs. We urge FDA to take appropriate action to remedy this situation including, for example, streamlining the regulatory requirements (see above regarding allowing a single PN for different sizes of the same brand), as well as pursuing technological improvements to the FDA/Customs computer systems and adopting those improvements as soon as possible.

Finally, FDA can facilitate the processing of PNs and reduce the "overload" to the system by making a single, technical change to the PN. Specifically, we propose eliminating the inclusion in the PN of a registrant's name and address together with its registration number. This information should be neither required nor necessary because FDA has access to same as the result of the facility's FDA registration.

Conclusion

We greatly appreciate the opportunity to provide our preliminary views concerning the implementation and operation of FDA's registration and PN interim final rules that have been in effect for the last twelve days. We look forward to supplementing our comments in March 2004 with the additional experiences that will be encountered over the next few months.

Once again, we commend FDA, particularly Deputy Director Carson, for his ever willingness to respond to our questions and provide guidance. We also commend FDA and CBP for their collaboration in streamlining the Bioterrorism Act's requirements and urge that this partnership continue in order to achieve even greater efficiencies.

If you have questions concerning our comments, please do not hesitate to contact us.

Sincerely,

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